

VZCZCXRO0944
PP RUEHRG
DE RUEHBR #0254/01 0611957
ZNR UUUUU ZZH
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FM AMEMBASSY BRASILIA
TO RUEHC/SECSTATE WASHDC PRIORITY 3693
INFO RUEHSO/AMCONSUL SAO PAULO 3634
RUEHRI/AMCONSUL RIO DE JANEIRO 7350
RUEHRG/AMCONSUL RECIFE 9164
RUEHAC/AMEMBASSY ASUNCION 7423
RUEHBU/AMEMBASSY BUENOS AIRES 6127
RUEHMN/AMEMBASSY MONTEVIDEO 7697
RUCPDOG/USDOC WASHDC

UNCLAS SECTION 01 OF 11 BRASILIA 000254

SENSITIVE
SIPDIS

DEPT FOR EB/TPP/IPE JENNIFER BOGER
DEPT PASS USTR FOR KATHERINE DUCKWORTH AND JENNIFER CHOE GROVES
DEPT PASS USPTO
USDOC FOR ITA/MAC/OIPR CASSIE PETERS
USDOC FOR ITA/MAC/WH/OLAC/MCAMPOS

E.O. 12958: N/A
TAGS: [KIPR](#) [ETRD](#) [ECON](#) [BR](#)
SUBJECT: BRAZIL: 2009 Special 301 Recommendation

REF: A) State 8410; B) 08 Brasilia 130; C) 08 Sao Paulo 242

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11. (U) Per reftel A, the following is Embassy Brasilia's input for the 2009 Special 301 Review of Brazil.

12. (SBU) Summary: Post recommends that Brazil be maintained on the Special 301 Watch List. GoB actions demonstrate a strong, inter-agency commitment to anti-piracy policy and consumer education. This commitment has yielded increases in some seizure statistics and a decrease in the percent of Brazilians who have purchased pirated or counterfeit goods.

13. (SBU) Despite making improvements, Brazil has not addressed all areas of effective IPR protection. Several IP-related draft laws remain stalled at various stages of the legislative process. Additionally, Post remains concerned about delays in patent and trademark processing, the national health vigilance agency's role in reviewing pharmaceutical patents and allowing the use of undisclosed test data, and widespread copyright infringements at university copy shops. End Summary.

Enforcement Efforts

14. (SBU) The quantity of counterfeit and pirated goods seized in 2008 is evidence of the GoB's continued focus on enforcement. According to GoB reports, partial year results for 2008 show more than 6000 total police inquiries into IPR violations (type of violation not specified) and R\$600 million (approximately US\$261 million) in counterfeit or pirated goods seized as a result of border controls. (Note: the policy statement does not specify what fraction of 2008 is included in the data, making it difficult to compare this number to 2007 when R\$1.5 billion of goods were seized). The same report claims that 410,639 units of counterfeit medicine were seized (partial 2008), compared to 322,601 in all of 12007.

15. (SBU) In a November 2008 study commissioned by the U.S. Chamber of Commerce and conducted by the Brazilian Institute of Public Opinion and Statistics (IBOPE), the most-seized products were: electronics (R\$79 million), cigarettes (R\$77 million), eyeglasses (R\$73 million), shoes (R\$65 million), and computer products (R\$58 million). Overall, according to the study, Receita Federal (the Brazilian customs and internal revenue service) destroyed 7,000 tons

of counterfeit and pirated products in 2008, with a total value of R\$228 million.

¶6. (SBU) In a report to the National Council to Combat Piracy (CNCB), Receita Federal registered 2008 contraband seizures totaling over R\$1.43 billion - a very slight decrease from 2007 when a record \$R1.05 billion of goods were seized. The number of anti-contraband operations also decreased slightly from 2,269 in 2007 to 2,137 in ¶2008. However, in the area of Foz de Iguacu, a well-known area for trafficking of contraband goods, Receita Federal seizures for 2008 totaled over US\$81 million, a 6 percent increase over 2007. According to CNCB, there has been a 70 percent decrease since 2004 in the total volume of pirated products that crossed the border in that area.

¶7. (SBU) For 2008, Policia Rodoviaria Federal (the Federal Highway Patrol) reported a 25 percent increase in confiscations of pirated media from the previous year (Note: confiscation of pirated media decreased 23 percent from 2006 to 2007, so the 2008 increase brings the number back almost equal with the 2006 figure. End Note.) Seizures of illegal computer products fell approximately 30 percent (from 122,881 units in 2007 to 85,585 units in 2008). Confiscations of electronics also decreased, by approximately 30 percent, falling back to just under 2006 levels. Confiscations of cigarettes (which fell by almost 50 percent) and drinks (which fell by approximately 40 percent) were well below even 2006 figures. The drop in confiscations could be due to an increase in the use of secondary roads by smugglers where Rodoviaria has less presence (ref B).

¶8. (SBU) The third major enforcement agency, the Brazilian Federal Police, reported 8,582 piracy investigations up to September 2008, on track to meet or surpass the number of investigations in 2007 (8,698). The Federal Police have not provided 2008 seizure information to Post. (Note: CNCB officials recently told Econoff

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that the organization's annual report containing consolidated federal agency enforcement statistics for 2007 and 2008 will not be available until April 2009. End Note.)

¶9. (SBU) Industry organizations are active in providing information to law enforcement and reporting the results of enforcement activities. According to the film and music industries' joint anti-piracy organization (APCM), 41 million pirated CDs and DVDs were seized in Brazil in 2008 (up 14 percent over 2007, with the number of seized DVDs doubling). The Motion Picture Association of America (MPA) reported a 400 percent increase in the seizure of hard goods in the state of Minas Gerais alone.

¶10. (SBU) The software industry also reports increases in seizure statistics for 2008. The Business Software Association's (BSA) May 2008 annual report (the most recent available) states that in 2007, 718 raids in Brazil resulted in the seizure of 2,253,546 CDs containing pirated software (150 percent more than in 2006). The Association of Brazilian Software Businesses (ABES) reports that for 2008 more than 1.6 million CDs containing pirated software were seized in the course of 754 operations (an increase of 5 percent over 2007). In one case, sixteen small shops selling pirated software products were fined R\$7 billion, 3000 times the value of the pirated software seized.

-- Border Crossings

¶11. (SBU) In Brazil's Tri-Border Area (TBA) (on the border with Argentina and Paraguay), Receita Federal seized 2000 vehicles in 2008(214 in August alone, a 26 percent increase over August 2007). The rise in vehicle seizures appears to be related to changing transportation patterns by smugglers who increasingly choose individual vehicles to transport their goods rather than caravans of buses. This change appears to be the result of a 2007 operation targeting buses crossing into Brazil in the TBA (538,038 products seized on buses from January to August 2007).

¶12. (SBU) A customs official in Foz de Iguacu (TBA) told Poloff that increased inspections will lead to a decrease in the overall number of incidents. However, Poloff's car was not inspected

crossing the Friendship Bridge between Brazil and Paraguay (a well-known entry point for counterfeit and pirated goods), nor did Poloff observe any other vehicles being inspected (ref C). Due to heightened enforcement efforts in the TBA (including the use of new surveillance tools like helicopters), industry contacts tell Post that smugglers are turning to other, more vulnerable entry points into Brazil.

-- Arrests and Convictions

¶13. (SBU) Citing difficulties in consolidating various state and federal databases, GoB interlocutors have thus far been unable to provide comprehensive statistics for arrests and convictions related to piracy and counterfeiting. Information provided to CNCP shows that up to September 2008, the Federal Police conducted 8,582 piracy/counterfeiting inquiries (compared to 8,698 for all of 2007) and 119 raids (compared to 191 for all of 2007), which resulted in 393 arrests (compared to 766 for all of 2007). The 2008 numbers for raids and arrests seem unlikely to surpass 2007. Piracy and counterfeiting charges were not segmented out from other charges such as income tax evasion. Rodoviaria Federal statistics also submitted to CNCP claim that 26,579 people were detained in 2008 during anti-piracy operations, but the statistics do not specify the number of eventual charges or convictions. (Note: last available statistics indicate that GoB reported only 14 convictions for piracy related crimes in 2005. End Note.)

¶14. (SBU) According to APCM, 195 people were convicted of copyright violations in Brazil in 2008. In a December 2008 ruling, a Sao Paulo court of appeals upheld the conviction and sentencing (imprisonment of approximately two years) of two Brazilians convicted of selling pirated CDs on a public thoroughfare. The court of appeals ruled that the defendants could not claim ignorance of anti-piracy laws as a defense since "it is well-known that selling pirate CDs is illegal, being the focus of large-scale campaigns in the media, reaching all echelons of society."

¶15. (SBU) In February 2008, a Sao Paulo court of appeals upheld a decision whereby a company in charge of administering the shopping

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center "25 de Marco" was held jointly liable when the stores on its premises sold counterfeit goods. Under this decision, the administering company had a duty to inspect the behavior of its vendors and their respective sales on its premises. The court issued a daily fine of approximately US\$31,000 for damages in case of noncompliance with the court's order.

--Counterfeit Agricultural Products

¶16. (SBU) In 2008, the Ministry of Agriculture (MAPA), Department of Intellectual Property and Agriculture Technology, conducted 15,411 investigations of suspected pirated seeds, which resulted in the suspension of 16.4 thousand tons of seeds and the assessment of 167 fines (ranging in value from R\$2000 to R\$1,814,548). MAPA analyzed 171 cases (up from 103 in 2007 and 71 in 2006). As a result of MAPA's enforcement efforts (including an internet tool for researching legitimate seeds), legitimate seed use in the major agricultural state of Rio Grande do Sul increased dramatically from 10 percent in 2007 to 46 percent in 2008.

¶17. (SBU) The Federal Police, in cooperation with the National Union of Agricultural Aviation Businesses (SINDAG), seized 340 tons of counterfeit agrochemicals and made 430 related arrests in 2008.

-- Counterfeit Medicine

¶18. (SBU) ANVISA, acting in cooperation with both federal and state authorities, reports thirteen cases of counterfeit medications in 2008 (an increase from 9 reported cases in 2007). GoB regulations call for usage of secure drug packaging and a distributors' registry, tools which have helped ANVISA to identify counterfeiting via irregularities in lot numbering and packaging. According to the Rodoviaria Federal, the number of units of counterfeit medication seized increased more than 50 percent from 322,601 in 2007 to 496,663 in 2008. Penalties for drug counterfeiters are stiff: 10-15

years without parole or amnesty plus a fine.

-- Raids on Known Markets

¶19. (SBU) State and federal enforcement authorities continued action against known marketplaces of counterfeit goods. Following raids in late 2007, two notorious markets located on Paulista Avenue in Sao Paulo, Promocenter and Standcenter, have not reopened. However, the selling of pirated and counterfeit goods has shifted to other markets in the same area, such as Paulista Center on Rua Pamplona.

¶20. (SBU) One raid in September 2008 seized 300,000 pirated media disks at a Sao Paulo shopping center. Eight people were arrested in connection with the raid. Another notorious market in Sao Paulo, Galeria Paje, was the target of a raid which seized 300,000 pirated media disks and 27 vehicles used to transport illegal goods. Police arrested eight people as a result of the raid and also seized three kilograms of cocaine and nine kilograms of marijuana. In November 2008, Brazilian law enforcement cooperated with Uruguayan counterparts in the border cities of Montevideo and Santana do Livramento. The seized blank DVD-R disks from both cities totaled over 100,000. (Note: CNCP told Econoff that updated information on raids of notorious marketplaces and other enforcement operations will be included in the organization's report due to be released approximately April 2009. End Note.)

Internet Piracy

¶21. (SBU) According to APCM, Brazil has the fifth most deficient broadband internet service in the world (behind Cyprus, Mexico, China, and India). 28 percent of internet connections are one megabyte per second (mbps) or slower, while most video streaming and social networking sites require speeds of at least 3.75 mbps to function optimally. 28 million Brazilians access the internet outside their own homes, most at internet cafes known as LAN (local area network) houses. These LAN houses are increasingly the focus of GoB efforts against internet piracy.

¶22. (SBU) In January 2009, an operation involving 600 police from 93 districts conducted 335 raids on LAN houses in Sao Paulo, acting on intelligence from APCM. 2,339 computers containing more than one

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million illegal files were seized. Draft Law 296/2008 was approved in October by the Committee on Science, Technology, Innovation, and Communication, and must now be voted on by the full Congress. The law would require LAN houses to maintain a registry of customers and must now be voted on by the full Congress.

¶23. (SBU) In February 2009, MPA representatives told Econoff that a lack of bandwidth and excessive licensing fees by the GoB have slowed the proliferation of internet pay-based media in Brazil. To air a television episode in Brazil, whether it is television or internet based, costs R\$3,000 in licensing fees. Without an immediate guarantee of profit, distributors are not interested in taking on this risk, and pirates are filling the market gap. MPA has targeted a number of websites providing illegal content through their internet service providers. In one recent case, MPA succeeded in shutting down three sites offering free subtitling for pirated movies.

¶24. (SBU) APCM reports that ten times more illegal files were removed in the first half of 2008 than during the same period in 2007. In addition, ABES and BSA report that 15,300 advertisements and 360 internet sites (up 48 percent from 2007) selling pirated or counterfeit products were removed from the airways. A pirate advertising illegal copies of films online was sentenced to 2 years imprisonment (reduced to one year community service) in a decision hailed by the MPA for its recognition that "the laws that govern the real world also apply to the virtual world." In February 2008, another internet pirate, whose website sold illegal copies of Beatles music, was arrested by the cybercrime division of the Sao Paulo police and sentenced to 18 months in prison. The sentence

reflects 140 repeated copyright infringements.

GoB Education and Training Programs

¶25. (SBU) While the GoB continues to emphasize enforcement as its primary means to combat piracy, it also appears committed to ongoing educational campaigns (many aimed at young adults and children) and training efforts for government officials. CNCP continued its involvement with the American Chamber of Commerce's elementary school program, "Projeto Escola Legal." The number of schools involved in the program quadrupled in 2008, from 15 to 62. More than 12,000 students and 300 teachers from five major cities participate in the program. CNCP also supports the U.S. Chamber's ongoing "Citizenship Game" (www.attitudeoriginal.com) that teaches youths and university students the importance of intellectual property rights in the context of social responsibility and gives them the opportunity to present their ideas on how to address IP infringement in Brazil. CNCP continues to promote the SINDIRECEITA (Union of Receita Employees) program "Pirate, I'm out. I only use the Original," also focused on college students, and the Federation of Industries of Rio De Janeiro (FIRJAN) "Authenticity" campaign to educate high school students. The Brazilian Office of Consumer Protection (PROCON) and interns at the Secretariat of Economic Development (SDE) have participated in CNCP-provided training.

¶26. (SBU) In 2008, ANVISA's internal training division continued participation in counterfeit medication seminars conducted by the private industry group National Anti-Piracy Forum (FNCP) in conjunction with Public Ministries in states throughout Brazil. An ANVISA official told Econoff that ANVISA's 2009 plans include expanding training to include judges. In 2009, ANVISA will attend an Asia-Pacific Economic Cooperation (APEC)-sponsored seminar in Mexico City on combating counterfeit medications, where one ANVISA participant will present on the topic of educational efforts to combat the spread of counterfeit medical products.

¶27. (SBU) In 2008, INPI held 36 courses on IPR at Brazilian universities and research institutes (an increase from 28 in 2007).

USG and Industry Provided Training

¶28. (SBU) Federal and state GoB officials have been receptive to USG funded and organized training. In 2008, 21 Brazilian officials participated in ten separate IPR training programs covering patents,

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trademarks and enforcement issues at the U.S. Patent and Trademark Office's (USPTO) Virginia-based Global Intellectual Property Academy (GIPA). In January 2009, GoB officials from the Ministry of Labor and Employment and the Ministry of Foreign Relations (MRE) participated in a GIPA course on copyright protection and enforcement. CNCP was active in assisting Post with disseminating information about invitations for training and facilitating communication with nominees. In February 2009, USPTO hosted six Brazilian trademark examiners for a two-week trademark training program as USPTO Foreign Examiners-in-Residence.

¶29. (SBU) In 2008, USPTO and INPI conducted a series of IP public awareness seminars ("IP Roadshow") in Porto Alegre, Salvador, and Sao Paulo, which were attended by over 300 Brazilian business owners, lawyers, government officials, and academics. USPTO and INPI have agreed to a second phase of the IP Roadshow to take place in May 2009, with seminars planned in Rio de Janeiro, Curitiba, and Manaus. The relationship between USPTO and INPI was solidified when the organizations signed a Memorandum of Understanding in July 2008, in an effort to enhance further cooperation on training and IP office administration.

¶30. (SBU) In July 2008, nine Brazilian officials participated in a DHS/ICE coordinated IP enforcement training program at the International Law Enforcement Academy in Lima, Peru.

¶31. (SBU) in September 2008, Post's Resident Legal Advisor (RLA), in conjunction with the U.S. Department of Justice's Cyber Crime and Intellectual Property Section (CCIPS), orchestrated IPR conferences in Florianopolis Brasilia. American judges, lawyers, and customs officials joined Brazilian prosecutors, judges, and law enforcement officers in presenting an overview of Brazilian IP law, as well as examples of investigations and cases ongoing in the Brazilian court system. In February 2009, cybercrime and intellectual property were the first topics in what will be a series of trainings aimed at combating crime in major Brazilian cities. The two-day training course in each city (Brasilia, Sao Paulo, and Rio de Janeiro) was funded by INL, DOJ and USSS and reached more than 800 Brazilian prosecutors, judges, and law enforcement officials. Highlighting key international IPR cases, the program focused on using technology to enhance the participants' investigations.

¶32. (SBU) At a January 2008 meeting with EmbOffs, Ministry of Agriculture officials expressed an active interest in USG help with patent protection and in streamlining the patent process for agricultural products. Post has applied for funding for MAPA officials to visit the United States for training and field observation related to seed and plant variety protection.

¶33. (SBU) Brazilian private industry organizations have also conducted extensive IPR training programs. In 2008, APCM along with ABES conducted 35 trainings for federal and state police, Receita Federal, and Rodoviaria Federal. APCM also coordinated with the Federation of Industries of the State of Sao Paulo (FIESP) to provide contraband identification training to Receita Federal inspectors at strategic ports such as Vitoria and Foz de Iguacu. In addition to offering training, the National Forum Against Piracy and Illegality (FNCP) maintains a consultations hotline which customs officials, police, and other law enforcement officials can use to seek information on improving their counter-piracy actions.

State Efforts

¶34. (SBU) The states of Brasilia, Pernambuco, Bahia, Sao Paulo, Rio de Janeiro, Rio Grande do Sul, and Minas Gerais all have specialized police units for the enforcement of intellectual property rights.

¶35. (SBU) Shortly after assuming office in 2007, the governor of Pernambuco, Eduardo Campos, publicly directed his state police force to cooperate with Federal Police in enforcing IPR statutes. In September 2007, the city of Blumenau in Santa Catarina state launched the "Municipal Council to Combat Piracy" in conjunction with the announcement of a State and Municipal Department of Education (APCM) coordinated program, "City Free of Piracy." APCM envisions replicating the Blumenau program in other states and already has plans to expand this program to the city of Uberlandia

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in Minas Gerais. CNCP has made "Cities Free of Piracy" a priority project for 2009.

¶36. (SBU) The states of Amazonas, Bahia, Ceara, Mato Grosso, Minas Gerais, Pernambuco, Santa Catarina, and Sao Paulo have innovation legislation containing specific references to the protection of intellectual property as a prerequisite for innovation.

University Copy-Shops

¶37. (SBU) According to the Brazilian Association for Reprographic Rights (ABDR), the University of Sao Paulo (USP) has an internal policy allowing the copying of entire books that are "not available on the market." According to an ABDR representative, what is considered "not available in the market" is very broad, but specifically includes books not written in Portuguese and not available for sale at campus book stores. In a February 2009 conversation with Emboff, the ABDR representative said that a late

2005 or early 2006 formal request for reconsideration presented to USP4s Dean resulted in a formal reply maintaining the rule.

¶38. (SBU) ABDR claims that the university justifies its internal rule by stating that access to knowledge and education are fundamentally protected under the Brazilian constitution. (Comment: Under Brazilian copyright law, "the one-time reproduction of small passages of a work for the copier's private use without the intention of making a profit" is allowed, but the Law does not define what constitutes a "small passage." End Comment.) The ABDR representative emphasized to Emboff that USP is setting a bad example, which has been mentioned in international fora and is being followed by other universities in Brazil including the Pontifical Catholic University of Sao Paulo and the Getulio Vargas Foundation of Sao Paulo. The representative says that despite CNCP action plans for the university textbook industry, no action has been taken to date.

¶39. (SBU) ABDR claims that though the number of university students in Brazil has increased 50 percent since 2002, sales figures for university books have decreased during the same time. Estimated losses for the Brazilian university book industry are around 3 times more than its earnings per year. The organization also states that students are beginning to illegally share copies of books using computer-based peer-to-peer file-sharing.

¶40. (SBU) In attempts to address the problem, ABDR has (for the past three years) run an awareness campaign for the Congress. To address student complaints that purchasing entire books is too expensive, ABDR and its member publishing companies have developed a web program called "Pasta do Professor" ("The Professor's File"), where students can legally purchase portions of books chosen by their professors. The Pontifical Catholic University of Minas Gerais will start using the program during the first term of 2009.

¶41. (SBU) During a February 2009 conversation, a copyright policy official at the Ministry of Culture (MoC) told Econoff that the GoB supports the right of individuals to access information and knowledge, which is often difficult due to the high cost of textbooks, despite their tax exempt status, as a result of low production runs. He asserted that more than 40 percent of the books needed by students are simply "not available" on the local market.

¶42. (SBU) According to the MoC official, the MoC is cognizant of the need to protect copyrighted material but also wants to meet the needs of Brazilian students. MoC hosted five public forums from December 2007 to November 2008 to solicit input for a copyright legislation reform. The MoC official said that a draft of the reform should be ready for public consideration by approximately March 2009. Some of the ideas being considered by the MoC to provide remuneration to authors are a collective management system or a tax on blank media and reproductive machines.

Patents, Trademarks and Data Protection

- Patents and Trademarks

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¶43. (SBU) INPI continues to have a substantial backlog in pending patent and trademark applications. However, INPI has taken concrete steps to improve processing of patent and trademark applications, including an ongoing upgrade of its outdated data processing systems. The GoB budgeted US\$100 million for INPI operations in 2008 and 2009 (compared to US\$40 million in 2004).

¶44. (SBU) The patent backlog is currently estimated at between 130,000 and 150,000 applications. According to INPI's President, there were 24,659 patent applications up to November 2008, surpassing the 24,081 patent applications received in all of 2007. Without opposition, patent applications are processed in an average of 8 years. INPI's goal is to reduce the processing time for patent applications to 4 years by 2010, pushed back from last year's goal to reduce the wait time to 4 years by 2009. Originally planned to

come online in 2008, INPI's electronic patent application filing system is now forecasted to be ready by the end of 2009.

¶45. (SBU) Since 2006, INPI has increased the number of patent examiners approximately 200 percent and increased median salaries 50 percent in order to retain experienced employees. According to an interview with the president of INPI, there are currently 238 patent examiners. The organization has already begun the process of hiring 95 new examiners and plans to add another 140 in 2010. With the new staff in place, INPI expects to have reviewed all backlogged applications by the first quarter of 2011.

¶46. (SBU) New patent examiners complete a two-year formal on-the-job training program that covers patent law and examination (including major national and international legislation and jurisprudence).

¶47. (SBU) Since 2007, INPI has been a WIPO-designated International Searching Authority (ISA) and International Preliminary Examining Authority (IPEA) under the Patent Cooperation Treaty (PCT) for international patent applications.

¶48. (SBU) INPI currently employs 110 trademark examiners and has not announced plans to hire more. The trademark backlog is estimated at approximately 470,000 applications. In 2007, INPI brought on-line a new electronic filing system (e-Marcas) to streamline trademark adjudications. Since then there has been a 15 percent increase in trademark applications (from 107,595 in 2007 to 124,660 in 2008). 52 percent of applications use the online system (compared to 44 percent of 2007 applications). According to INPI, new trademark applications are now being initially processed within 16 to 18 months.

¶49. (SBU) In 2006, Brazil announced plans to join the Madrid Agreement Concerning the International Registration of Marks ("Madrid Protocol"), but the executive branch has yet to submit this proposal to the Brazilian Congress for approval. Nonetheless, INPI has undertaken new training and reorganization efforts in anticipation of Brazil's eventual enactment of the Madrid Protocol. For that reason, six INPI trademark examiners participated in a September 2008 training at the German patent office.

--Patents for Pharmaceutical Products

¶50. (SBU) Law 10196 (2001) requires ANVISA's prior consent before the issuance of a pharmaceutical patent, raising concerns of a possible conflict with Article 27 of the TRIPS agreement. U.S. companies have complained of lengthy delays in getting ANVISA approval for their pharmaceutical and medical device patent applications. On June 23, 2008, ANVISA issued a resolution standardizing, to some extent, the procedures and timeline for review of pharmaceutical patent applications. Nonetheless, ANVISA's role in reviewing pharmaceutical patent applications remains non-transparent and has contributed to an increasing backlog in the issuance of patents. ANVISA claims that its reviews take no more than 120 days with only a three percent rejection rate.

¶51. (SBU) Medical device manufacturers continue to voice concerns over a 2006 ANVISA regulation requiring disclosure of data prior to approval of medical devices that they believe to be overly burdensome and threatens to infringe on the companies' proprietary financial information.

--Polymorphs and Second-Use Drugs

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¶52. (SBU) In April 2008, INPI issued preliminary internal guidelines on the patenting of polymorphs and second-use inventions for public comment. The decision to issue such guidelines, which suggested that patents in the area might be allowed by INPI, was not supported by the Ministry of Foreign Affairs or other ministries and created a public schism on the issue. According to press reports, the Ministry of Development, Industry, and Commerce's Secretary of Industrial Technology noted that although INPI has the power to define technical and legal guidelines for the examination of

patents, the final word on the subject lies with the Interministerial Group on Intellectual Property (GIPI). An official of the Foreign Ministry commented that there is no obligation to grant polymorph patents in the WTO TRIPS Agreement. A Ministry of Health representative noted that if such patents were permitted, there would be a risk that active substances of various drugs, which today are in the public domain, would be unavailable, preventing the production of generics.

¶53. (SBU) On December 1, 2008, GIPI held a meeting on the issue of patenting polymorphs and second-use inventions. The government committee unanimously adopted the decision that granting patents in this field does not meet the national interest. The only dissenting opinion was voiced by INPI, which is not a member of GIPI. INPI noted that Brazil's patent law does not suggest any restrictions on pharmaceutical products, so long as they meet patentability criteria.

¶54. (SBU) In January 2009, USPTO held a digital video conference with INPI to discuss U.S. practice in patenting polymorphs. USPTO is providing further follow-up information on U.S. practice. At this time, there is no pending legislation to revise Brazil's patent law implementing GIPI's decision. (Comment: IPR attach anticipates that GIPI's decision may instead be enforced during ANVISA's review of pharmaceutical patent applications. End comment.)

-- Major Roadblocks to Biotech Product Approvals Removed

¶55. (SBU) In March 2007, law 11460 changed the requirement for approval of commercial licensing of genetically modified organisms (GMOs) and GMO derivatives by Brazil's 27 member National Technical Commission of Biosafety (CTNBio) Board from a two-thirds majority to an absolute majority. This removed an impediment to commercial licensing of GMOs and GMO derivatives, since the board is heavily influenced by environmentalists and anti-biotech groups. Subsequently, in June 2008, the National Biosafety Council (CNBS) decided that it will only review administrative appeals that are of national interest, involving social or economic issues, as per the Brazilian Biotech Law. CNBS considers all approvals of biotech events by CTNBio as conclusive and will not evaluate technical decisions on biotech events that are approved by CTNBio. This is an important decision that, along with the change in majority voting, eliminates a major barrier for approval of biotech events in Brazil. Since then, at least three commercial biotech applications (GMO corn) have been approved.

-- Data Protection

¶56. (SBU) Brazil's Industrial Property Law (9279/1996; Art. 195, XIV) provides for civil and criminal penalties for "anyone who...divulges, exploits, or utilizes, without authorization, results of tests or other undisclosed data whose preparation involves considerable effort and that were submitted to government agencies as a condition for obtaining approval to commercialize products." However, this provision also provides an exception whereby disclosure by government agency is permitted "when necessary to protect the public." Law 10603/2002 mandates the protection of test data for veterinary pharmaceuticals and agrochemicals for 2-5 years (depending on whether it is a new or known chemical entity). This law does not cover pharmaceuticals for human use. According to Article 7 of this law, if the product is not commercialized within two years of the date of sanitary registration, third parties may request use of the data for registration purposes.

¶57. (SBU) In several cases, ANVISA has granted marketing approval to generic drug manufacturers based on undisclosed test results and other confidential data submitted in connection with approval of the original drug, raising concerns of consistency with TRIPS Article 39.3. ANVISA has taken the position that reliance on the previously

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granted marketing approval is not a violation of Brazil's unfair competition laws.

¶58. (SBU) Lack of data protection and transparency at ANVISA played a critical role in the copying and marketing of a generic drug based

on a U.S. company's invention. In July 2007, the U.S. company applied for marketing approval for a drug, but was never issued a decision. Instead, in February 2008, ANVISA granted approval to a Brazilian firm to market the same drug, though that firm had not conducted any clinical test trials. According to ANVISA officials, ANVISA has the right to waive requirements for submitting clinical test data on a case-by-case basis.

¶59. (SBU) The Brazilian patent in this case was issued in 2005 but nullified by INPI in 2006 for lack of inventiveness. A February 2008 administrative appeal to stay the marketing of the generic received no response, despite a Brazilian law that says administrative appeals must be tried within 30 days of receipt by the Permanent Commission for the Analysis of Appeals (COREC). According to the U.S. company, the only remaining remedy is to challenge INPI for restoration of its patent on the drug in question. If granted patent rights, the company could seek possible infringement action against the Brazilian firm.

-- Compulsory Licensing

¶60. (SBU) Invoking TRIPS provisions, on May 4, 2007, Brazil issued a compulsory license for Merck Sharp & Dohme's anti-retroviral drug efavirenz (brand name: Stocrin), used in treating HIV/AIDS, after a breakdown in negotiations with the company. The Brazilian government cited a need for cost savings in its universal HIV treatment program as justification for the compulsory license. A GoB official stated to Emboffs at a January 2008 meeting that the drug's patent was one of over 400 pipeline patents, and, thus, was already in the public domain when the patent was issued. Post is not aware at this time of any other imminent compulsory licensing actions by the GoB.

----- Legislation -----

¶61. (SBU) While the GOB has not joined the WIPO Copyright Treaty (WCT) or the WIPO Performers and Phonograms Treaty (WPPT), industry groups and GOB agencies continue to seek to strengthen existing intellectual property legislation.

¶62. (SBU) In May 2008, several members of the Brazilian Congress formed a commission (CEPIRATA) to examine 25 pending draft laws related to the protection of intellectual property. At a June forum attended by Econoff, CEPIRATA representatives said they were committed to pushing "umbrella" legislation and that they would focus their attention on draft law 333 introduced in 1999. That law would stiffen the criminal penalties for piracy, but remains stalled in the Congress. The draft law was shelved in 2006. In November 2008, a resolution was submitted requesting its urgent reconsideration. Post is not aware of any further action since then.

¶63. (SBU) Private sector attendees of the forum agreed that the GoB should concentrate on permitting sampling of suspected counterfeit goods (rather than requiring testing of every item), permitting quick destruction of goods once counterfeiting is confirmed (even when criminal investigation is not yet concluded), reversing the burden of proof in cases involving customs evasion, and increasing criminal sentences.

¶64. (SBU) Trademark counterfeiting is currently punishable with imprisonment of three months to one year, or a fine. A 2007 draft law that would have increased penalties for trademark violations was rejected in March 2008, but its provisions were appended to a 2003 draft law that is still being considered by the congressional committee on the Constitution, Justice, and Citizenship. The 2003 bill would establish IPR violations as public actions, make it illegal to publicize a sale or rental of a copyright-infringing work, and establish criminal copyright fines of R\$10,000 to R\$50,000. The 1999 draft bill mentioned in paragraph 58 above would increase prison terms for trademark violations from one to four years, and another 2007 draft law would allow for imprisonment from

two to six years.

¶65. (SBU) Law 11898/2009, commonly known as the "Sacoleiros Law," passed in January 2009 and establishes a 42 percent flat tax for items imported by the informal commercial importers known as sacoleiros. The bill allows importation of DVDs and CDs, mp3 players, and other goods that are among the most commonly pirated products. Industry observers fear that the law, though not specifically related to piracy and counterfeiting, will ease the entry of illegal products into Brazil. The Executive President of the Brazilian Institute for the Defense of Competitiveness has predicted that the law will triple piracy rates in Brazil, but no statistics are available to support that conjecture.

¶66. (SBU) Representatives from MPA told Econoff that the organization's suggested amendments to the Sacoleiros Law (most importantly to make blank media ineligible for the law's flat tax regime) were rejected by the GoB. MPA is concerned that by formalizing the sacoleiros' imports, the GoB may de facto legitimize IP violators.

- Optical Disk Regulations

¶67. (SBU) Brazil does not have any regulations on optical media manufacturing for the purpose of controlling domestic production or any laws or regulations requiring the use of source identification (SID) codes in the mastering or replication of optical media. There are approximately a dozen optical disc plants in Brazil, which appear to be operating legitimately and are not a significant source of pirated media. In a February 2009 meeting, a representative of MPA told Econoff that 500 million CD-Rs and DVD-Rs were imported into Brazil in 2008, but that only 30 million were used for legal purposes. Most of the blank media is imported from Taiwan and Hong Kong.

----- Consumer Perception -----

¶68. (SBU) A September 2008 study of consumer perceptions commissioned by the U.S. Chamber of Commerce concludes that changing consumer habits combined with decreased supply of pirated and counterfeit goods (due to increased enforcement) have contributed to a decrease in overall piracy rates in Brazil. In the categories of tennis shoes, clothing, and toys, there was a 38 percent combined reduction in spending on counterfeit products. Looking at a broader array of ten product categories, spending on counterfeit products decreased 5 percent, with a dramatic reduction of 35 percent in Rio de Janeiro set off by a 46 percent increase in Belo Horizonte.

¶69. (SBU) Respondents (chosen from different age groups and education levels) were asked about their general attitudes toward and intentional consumption of pirated products. 34 percent of respondents said they never purchase pirated goods (up from 24 percent in 2007), while 11 percent said they always do so (down from 15 percent in 2007). 77 percent agreed that purchasing counterfeit or pirated products damages the collection of taxes and diminishes the government's ability to invest in health, education, housing, etc. Despite that knowledge, 65 percent of respondents said they would purchase pirated products if the impact of doing so was only a decrease in tax revenue. 72 percent would not purchase pirated goods if they knew that piracy financed organized crime; 90 percent would not purchase pirated goods if they knew that doing so would harm themselves or their families.

¶70. (SBU) In August 2008, Rio de Janeiro's Commerce Federation (Fecomercio - RJ) and Ipsos Public Affairs released a report entitled "The Consumption of Pirated Products in Brazil." According to the report, there was a 5 percent increase in the percentage of Brazilians that bought such products (47 percent in 2008, 42 percent in 2007). There was a minor decrease in the population's willingness to buy pirated CDs - from 86 to 83 percent - and a considerable increase in the willingness to buy pirated DVDs - from 53 to 69 percent. The population's willingness to buy counterfeit watches, toys, glasses and apparel decreased from 2007 to 2008.

----- Future Plans

¶71. (SBU) According to CNCP officials, the organization spent much of 2007 in "planning mode." CNCP used the planning time to prioritize several projects from its 99-point action plan to combat piracy. In December 2008, CNCP's president announced the following six priorities for 2009.

-Increase enforcement against pirated products at notorious markets and search for alternative commerce opportunities for vendors.

-Develop an interactive CNCP website, including educational material.

-Fight piracy by offering incentives for municipal enforcement authorities to create cities "free of piracy."

-Raise consciousness among vendors and merchants of the damage done by piracy.

-Create partnerships with internet providers to prevent the distribution of pirated products.

-Work with states to create new police units specialized in combating piracy and strengthen already existing units.

¶72. (SBU) Comment: GoB efforts to improve the adequacy and effectiveness of intellectual property protection are multi-faceted and include a number of agencies and organizations. While some in GOB have resisted in-depth discussion on IPR issues, Mission has made progress in reframing the issue as important to innovation and competitiveness. Mission's working relationship with CNCP has evolved over recent years and today is excellent. Relationships with ANVISA, INPI, and the Intellectual Property Division of MRE have also improved dramatically and currently reflect a previously unknown degree of cooperation on IPR efforts. There are clearly many challenges and opportunities for improvement of the legislative framework and overall IP protection in Brazil. However, the GoB is increasingly active in this area, and Post is encouraged by the progressively more cooperative and receptive nature of working relationships with various GoB agencies. End Comment.

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